DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35
Public Health Service
D1239B

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

March 5, 1997

WARNING LETTER
CIN-WL-96-115

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Paul Strauss, Owner
Equinox Botanicals
33446 McCumber Road
Rutland, OH 45775

Dear Mr. Strauss:

This is in reference to **The Golden Salve with propolis** and six other products which are manufactured and marketed by your firm.

These products are drugs (section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act)) because their labeling states that they are intended to treat, cure, or prevent disease. Since these products are offered for sale over-the-counter (OTC), they are required to comply with general regulations covering OTC drugs (21 Code of Federal Regulations part 330) and specific OTC drug product monograph(s) (including one tentatively adopted), or be covered by an approved new drug application. If this is not the case, the product is an unapproved new drug which may not be legally marketed in the United States. Our comments are as follows:

"The Golden Salve with Propolis"

This product is labeled "for wounds, burns, infections, skin rejuvenation, sunburn, rashes, chapped skin, diaper rash, cradle cap, dry noses or other skin abrasions."

"Propolis Extract"

This product is labeled as "a remarkable healing agent for ulcers, flus, colds, gum problems and infections, including staph infections." Note: "Labeling" includes information in product catalogues and promotional brochures.

"Echinacea Extract"

This product is labeled as "a herbal antiseptic and has been used for eczema, acne, and infections."

"Comfrey Root Extract"

This product is labeled "for coughs, respiratory problems, intestinal irritation, ulcers, broken bones, bruises, burns and wounds."

"Goldenseal Extract"

This product is labeled as "a powerful antiseptic and has been used for infection and stomach conditions."

"Calendula Extract"

This product is labeled for "use in fever, infection, boils, and abscesses."

Based on their labeled indications, the above products are subject to one or more of the following Final Rules:

- Topical Antimicrobial (Acne) Products (21 CFR 333.320)
- Miscellaneous External Drug Products, Subpart H-Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis (21 CFR 358.710)
- Drug Products Offered OTC for the Treatment of Boils (21 CFR 310.531) Oral Health Care Drug Products (21 CFR 310.545(a)(14)
- Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (21 CFR 341.14).

In addition, no OTC drug products are known to be effective for treating broken bones.

"Herbal Smoke Tobacco Substitute"

This product contains leaves of mullein, coltsfoot, lobelia, and peppermint, and is labeled to 'relieve congestion of the lungs', and as "a healthy substitute for tobacco and lobelia in the mix can curb the desire for nicotine for those who wish to give up the habit."

Based on its labeling to relieve congestion of the lungs, this product is subject to the Final rule for OTC Expectorant Drug Products, (21 CFR 341.18), and its labeling to curb smoking, is subject to the Final Rule for Smoking Deterrent Drug Products (21 CFR 310.544).

None of these products conform with the appropriate Final Rule(s) because they do not contain allowed ingredients. Thus, they are new drugs (section 201(p) of the Act) which may not be legally

marketed in the United States since they are not approved (section 505). They are also misbranded (section 502(f)(1) of the Act) because the labeling fails to bear adequate directions for use. Products which are labeled as antiseptics for external use are also misbranded (section 502(f)(2)) because they do not contain the caution statement required by 21 CFR 369.20.

The above list of violations is not intended to be an all-inclusive of those that exist at your firm. It is your responsibility to ensure that the drug products you market meet all requirements of the Act and its implementing regulations. Federal Agencies are advised on the issuance of Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific actions you will take to correct the violations. Your response should include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio, 45202-1097, to the attention of Charles S. Price, Compliance Officer. You should direct your questions concerning this letter to Mr. Price at 513-684-3501.

Sincerely,

John R. Marzilli
District Director
Cincinnati District

CSP/pjk